

Mitchell E. Daniels, Jr. Governor

Gregory N. Larkin, M.D., F.A.A.F.P. State Health Commissioner

DATE:

September 20, 2010

TO:

All Local Health Departments

Attn: Chief Food Inspection Officer

FROM:

A. Scott Gilliam, MBA, CP-FS Director, Food Protection Program

SUBJECT:

KiloSports Inc. Recall

## **SUGGESTED**

**ACTION:** 

Unclassified Recall; 60 Count bottles of Clomed because it may contain an Aromatase

Inhibitor; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the product being recalled may be distributed in the State of Indiana. Clomed was distributed throughout the United States and could be purchased by consumers via retail stores, mail order and Internet Sales. Detail information is not available at this time. In addition, if any recalled product is found,

please notify this office at 317-233-7360.

\*

## **Recall -- Firm Press Release**

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

## Kilosports Inc. Issues Voluntary Recall of Clomed

Contact:

KiloSports Inc. 1.480.545.3489

FOR IMMEDIATE RELEASE -- September 14, 2010 - KiloSports Inc. of Phoenix, AZ is recalling 60 Count bottles of Clomed because it may contain an Aromatase Inhibitor. KiloSports Inc. has been informed by the US Food and Drug Administration (FDA) that adverse events associated with the use of Aromatase Inhibitors could include the following: decreased rate of bone maturation and growth, decreased sperm production, infertility, aggressive behavior, adrenal insufficiency, kidney failure, and liver dysfunction. Consumers with liver, kidney, adrenal, or prostate abnormalities are at higher risk for developing adverse events. The FDA concludes that products containing aromatase inhibitors have a increased probability of developing adverse reactions in at risk consumers.

Clomed was distributed throughout the United States and could be purchased by consumers via retail stores, mail order and Internet Sales.

Clomed comes in plastic black bottles with black safety caps contains 60 Count white or clear capsules with the UPC Code (8 58515 00265 7 & 8 5851500096 7) All lot numbers are being affected by this voluntary recall.

KiloSports Inc. has received no reports of any adverse effects or Illness of any type since first marketing **Clomed** since 2005.

Consumers who have purchased **Clomed** are asked to return it to the place of purchase for a full refund. Consumers with any questions may contact the company at 1.480.545.3489 9AM – 5PM Monday - Friday.

Adverse reaction or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program online, by regular mail, or by fax. Online: www.fda.gov/MedWatch/report.htm. Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form. Fax: 1-800-FDA-0178.

#

Photos: Product Labels<sup>9</sup>